



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

WOLLMER ET AL.

Atty. Ref.: 613-101; Confirmation No. 1945

Appl. No. 10/563,828

TC/A.U. 1618

Filed: May 8, 2006

Examiner: Samala

For: MICROEMULSIONS AND ITS USE FOR PREVENTING AIRWAY DISEASES

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January 21, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE

Applicants hereby submit this in response to the Office Action mailed November 20, 2008 ("Office Action").

A response to the Office Action was originally due December 20, 2008. Applicants hereby petition for a one-month extension of time in which to submit a response or an amendment in response to the Office Action. The fee for a one-month extension of time is \$65 (small entity) and a check in that amount is enclosed. Therefore, the deadline for responding to the Office Action is now January 21, 2009 (January 20, 2009 being a holiday, inauguration day). Accordingly, this Amendment and Response is being timely filed.

Responsive to the request to select a single inventive concept, the applicant elects the invention classed as Group I, i.e. claims 19-27 directed to a reversed phase microemulsion comprising 5 to 35 wt.% of a non-polar animal or vegetable oil, 10 to 55 wt.% of at least one polar solvent selected from the group consisting of water, a buffer, an alcohol, and mixtures thereof, and at least one surfactant selected from a polysorbate, a polyoxamer and a fatty acid

polyoxyethylene, wherein the microemulsion further comprises 20-50 wt.% of a monoacyl glycerol.

However, the applicant also wishes to traverse the restriction requirement on the basis of the following comments:

The Examiner has stated that the application contains several inventions or groups of inventions which are not linked by a single general inventive concept (item 1 of Office Action). It is asserted in item 2 of the Office Action that the Examiner regards the groups of inventions as lacking the same or corresponding special technical feature, because the special technical feature shared by Groups I-IV, namely the reversed phase microemulsion, is not viewed as presenting a contribution over the prior art. The Examiner states that the reversed phase microemulsion is described in US 6,506,803, Baker *et al.*

It thus appears that the Examiner does not consider the reversed phase microemulsion of claim 19 to be novel over Baker *et al.*, and therefore considers that the claims are not unified because the unifying feature, the reversed phase microemulsion, is known. This seems to be the sole basis upon which the Examiner has issued the restriction requirement.

Thus, the crucial issue is whether or not the reversed phase microemulsion is novel over the disclosures of Baker *et al.* If the microemulsion is novel then Groups I-IV share a special technical feature which provides a contribution over the prior art and a single general inventive concept: a microemulsion; devices containing that same microemulsion; and a method of trapping airborne particles using that microemulsion. Therefore there can be no need to restrict the application in any way.

The applicant would like to remind the Examiner that the question of novelty over the prior art, and specifically over Baker *et al.*, was discussed in the interview of May 29, 2008, prior to the filing of the response dated August 20, 2008. As a direct result of these discussions, the claims were amended to recite a reversed-phase microemulsion, i.e. a water-in-oil microemulsion. Water-in-oil emulsions are distinct from the usual oil-in-water emulsion and are immediately recognized as different by those skilled in the art.

In contrast to the claimed invention, an oil-in-water emulsion is explicitly specified in the abstract and text of Baker *et al.* US 6,506,803, for example column 1, lines 21-28, column 5, lines 24-29 and column 10, lines 28-35: " the present invention relates to methods and compositions

for decreasing the infectivity of pathogenic organisms in foodstuffs... accomplished by contacting the pathogenic organism with an oil-in-water nanoemulsion..."; column 11, lines 20-24: "Suitable surfactants include... a variety of ionic and nonionic surfactants, as well as other emulsifiers which are capable of promoting the formation of oil-in-water emulsions. Any surfactant that allows the oil phase to remain suspended in the water phase can be used."

The applicant has previously submitted an evidentiary declaration from inventor Per Wollmer made August 18, 2008 to confirm that the microemulsions of the present invention are reversed phase, i.e. water-in-oil rather than oil-in-water and to support the distinction of water-in-oil emulsions from the usual oil-in-water emulsions, which are to be expected in the art.

The Examiner has cited disclosures by Baker *et al* in the abstract and in column 10, lines 65-68. In the abstract, Baker *et al* refer to an oil-in-water emulsion comprising an oil, a surfactant and an organic phosphate-based solvent. In columns 10-11 this disclosure is expanded, and an emulsion is disclosed which comprises 5-50 vol.% aqueous phase, 30-90 vol.% oil, which comprises 3-15 vol.% of an organic solvent, and 3-15 vol.% of at least one surfactant, which must be capable of promoting the formation of an oil-in-water emulsion. This equates to an emulsion having 8-65 vol.% of aqueous phase and surfactant (wherein 3-15 vol.% is surfactant), 15-87 vol.% oil, and 3-15 vol.% organic solvent.

In contrast, the present invention comprises 10-55 wt.% of at least one polar solvent and at least one surfactant, 5-35 wt.% oil and 20-50 wt.% polar lipid (monoacyl glycerol). There is no stipulation to include an organic solvent. Instead, there is a stipulation that 20-50 wt.% of a polar lipid, a monoacyl glycerol must be included, which is neither disclosed nor suggested by Baker *et al*.

As stated in the inventor's evidentiary declaration, the lipids in the formulations used in the Examples of the subject application (glycerol monooleate and sesame oil), have a negative spontaneous curvature and cannot form the positive curvature required for an oil-in-water microemulsion. All examples are thus necessarily reversed phase water-in-oil type microemulsions as is evident to one skilled in the art.

Furthermore, the solvent content, 10 to 55% by weight of the composition (corresponding to the proportion of solvent illustrated in the Examples of the application as filed) is a relatively

low proportion of solvent and will result in reversed phase microemulsions rather than normal phase.

The lipids in the formulations do not - either alone or in combination - possess the intrinsic spontaneous curvature required to form normal phase structures. Neither do they have solubilities in aqueous fluids allowing them to form the curvature required to generate phase-separated normal structures. Thus, the components used by the present inventors and claimed in the present application *cannot* be the same as those disclosed in Baker because they do not satisfy the requirements of Baker that must be capable of promoting the formation of an oil-in-water emulsion. The components of Baker have different inherent properties to those currently claimed and thus they *must* be different.

Both phase behavior and solubility are collective properties of the mixture, and the advantages of reversed phase microemulsions include retention of their structure on mixing with an aqueous solution which conveys the ability to form a barrier layer.

Counsel reminds the examiner he is obliged to accept the evidentiary declaration of record unless he is in possession of facts to disprove the statements made in the declaration.

The applicant submits that the reversed phase microemulsions of the current invention are clearly novel over the oil-in-water emulsions of the prior art, in particular those disclosed by Baker *et al.* This is not least because if the components of Baker and the present invention were the same then they would show the same phase behavior; they do not and thus the invention must be different from Baker.

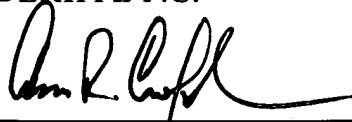
For the reasons set out herein, the applicant submits that the reversed phase microemulsions of the current application are novel over the prior art, including that of Baker *et al.*, and therefore there can be no need to restrict the application in any way.

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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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